REMARKS

I. Introduction

Applicants thank Examiner McKane for the courtesies extended to the undersigned at the personal interview conducted on August 13, 2003. Reconsideration and withdrawal of all grounds of rejection in light of the amendments and remarks set forth herein are respectfully requested.

II. The Amendment and Pending Claims

By the present amendment, claims 1, 4-13, 15-22, 25-28, 30, 34, 36-45, 47-54, 59-68, 70-77 and 80-83 have been amended, claims 35 and 84-172 have been cancelled and claims 173-196 have been added. Accordingly, claims 1-28, 30, 34, 36-83 and 173-187 are pending. Additionally, the specification has been amended to correct a minor clerical error. The amendments do not introduce new matter.

Independent claims 1, 30 and 34 have been amended to recite that "said effective rate is not constant for the duration of the sterilization procedure." Support for this amendment may be found, for instance, in the originally filed specification at page 14, lines 10-12. Moreover, in the Interview Summary dated August 13, 2003, the examiner stated that the examiner "would allow a limitation of 'not constant'." Thus, the present amendment to each of independent claims 1, 30 and 34 introduces no new matter.

III. The Rejections

In the outstanding office action, the examiner made the following grounds of rejection:

(A) claims 1, 2, 4-6, 11-18, 20-22 and 25-28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sakai in view of Hackett;

(B) claims 1, 2, 4-8, 14, 19, 21, 22 and 25-28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chanderkar in view of Hackett;

(C) claims 1, 2, 4-6, 9, 14, 18 and 20-28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baquey in view of Hackett;

(D) claims 1, 2, 5, 10, 14, 19, 22 and 25-28 under 35 U.S.C. § 102(b) as being anticipated by Field in view of Hackett;

(E) claim 3 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sakai or Chanderkar or Field all in view of Hackett as applied to claim 1 and further in view of Horowitz;

(F) claims 30, 34-38, 43-50, 52-54, 57-61, 65-73, 75-77, 80-88, 92-100, 102-104, 107-116, 120-128, 130-132, 135-139, 141-147, 152-159, 161-163, 166-170 and 172 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sakai in view of Horowitz;

(G) claims 30, 34-40, 46, 48, 49, 51, 53, 54, 57-63, 69, 71, 72, 74, 76, 77, 80-90, 96, 98, 99, 101, 103, 104, 107-118, 124, 126, 127, 129, 131, 132, 135-138, 140, 149, 155, 157, 158, 160, 162, 163, 166-169, 171 and 172 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chanderkar in view of Horowitz;

(H) claims 30, 34-38, 41, 46, 48-50, 52-56, 58-61, 64, 69, 71-73, 75-88, 91, 96, 98-100, 102-113, 119, 124, 126-128, 130-138, 141-144, 150, 155, 157-159, 161-169 and 172 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baquey in view of Horowitz; and

(I) claims 30, 34, 35, 37, 42, 46, 48, 49, 51, 57, 58, 60, 65, 69, 71, 72, 74, 77, 80-85, 87, 92, 96, 98, 99, 101, 104, 107-113, 120, 124, 126, 127, 129, 132, 135-138, 141-144, 151, 155, 157, 158, 160, 163, 166-169 and 172 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Field in view of Horowitz.

Applicants respectfully traverse each of these rejections for the reasons set forth in detail below.

A. Sakai in view of Hackett

The examiner rejected claims 1, 2, 4-6, 11-18, 20-22 and 25-28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sakai in view of Hackett. Independent claim 1, from which claims 2, 4-6, 11-18, 20-22 and 25-28 depend, has been amended to recite that "said effective rate is not constant for the duration of the sterilization procedure." Neither Sakai nor Hackett teach or suggest a method for sterilizing a biological material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

The undersigned notes that in related U.S. Patent Application Serial Number 10/197,248, the examiner commented on the meaning of the term "not constant" in connection with the rate

of irradiation. In an office action issued with respect to that application, the examiner asserted that the term "not constant" may include variation(s) in the rate of irradiation resulting from natural decay of the source material over the duration of sterilization. For reasons set forth below, such a construction of that term is clearly not consistent with the present specification. *See* MPEP § 2111 (During patent examination, the pending claims must be "given the broadest reasonable interpretation consistent with the specification.") (emphasis added). To be consistent with the specification, the term "not constant" must indicate a variation in the rate of irradiation that is greater than that resulting from natural decay of the source material over the duration of the sterilization procedure.

As stated in the original specification, "[p]referably the rate of irradiation is constant for the duration of the sterilization procedure." (page 14, lines 10-12). In order for this passage to be consistent with the remainder of the specification, particularly the examples, the term "constant" must be interpreted to include variation(s) in the rate of irradiation resulting from natural decay of the source material over the duration of the sterilization procedure. Examples 1-11 of the original specification each relate to the irradiation of biological materials with a ^{60}Co source. Each of these examples teaches that the biological material was irradiated at a single (and therefore constant) rate of irradiation for a defined period of time (the time is either explicitly recited or may be determined by dividing the total dose by the dose rate). The single (constant) rate of irradiation recited in each of examples 1-11 must, therefore, include any variation in the rate of irradiation arising from natural decay of the source material that would

have occurred over the defined period of time. Thus, to be consistent with the examples in the specification, the term "constant" irradiation clearly encompasses all such variation(s).

Since the term "constant" includes any variation in the rate of irradiation resulting from natural decay of the source material over the duration of the sterilization procedure, it follows that the term "not constant" must refer to a change in the rate of irradiation greater than that resulting from natural decay of the source material over the duration of the sterilization procedure. Otherwise, any distinction between the two terms is lost and the term "constant" becomes subsumed by "not constant." Where, as here, the original specification distinguishes between "constant" and "not constant" rates of irradiation, such a reading cannot be correct as it is utterly inconsistent with the remainder of the specification and vitiates the term "constant."

Moreover, the examiner's construction of the term "constant" is also inconsistent with the state of the art. More specifically, the references relied upon by the Examiner in the outstanding grounds of rejection employ ^{60}Co as the source material. Because the half-life of ^{60}Co is about 46,164 hours (about 5.27 years), it takes about 23,083 hours for one half of the ^{60}Co present at the initiation of irradiation to degrade. Over the comparatively short period of irradiation necessary to sterilize a biological material (typically, less than 24 hours), any variation(s) in dose rate due to decay would not be detectable to the number of significant digits recited in the original specification (dose rates are give to one decimal place) or the cited references.

For example, Sakai teaches a method wherein irradiation is carried out at a (constant) dose rate of 3.45×10^4 rad/hr (0.345 kGy/hr). Being one skilled in the art, Sakai clearly would

have recognized the potential for a change in dose rate due to natural decay of the source material. Yet Sakai makes no mention of such variation(s) in the disclosure of the dose rate employed. Thus, the references cited by the examiner show that those skilled in the art understand "constant" dose rates to include any variation(s) due to natural decay. (Similarly, every reference cited by the examiner uses the same language as Sakai with respect to any discussion of dose rates, i.e., there is no discussion of any variation in the dose rate due to natural decay yet such decay would have been known by those skilled in the art).

B. Chanderkar in view of Hackett

The examiner rejected claims 1, 2, 4-8, 14, 19, 21, 22 and 25-28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chanderkar in view of Hackett. Independent claim 1, from which claims 2, 4-8, 14, 19, 21, 22 and 25-28 depend, has been amended to recite that the "said effective rate is not constant for the duration of the sterilization procedure." Neither Chanderkar nor Hackett teach or suggest a method for sterilizing a biological material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

C. Baquey in view of Hackett

The examiner rejected claims 1, 2, 4-6, 9, 14, 18 and 20-28 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baquey in view of Hackett. Independent claim 1, from which claims 2, 4-6, 9, 14, 18 and 20-28 depend, has been amended to recite that the "said effective rate is not constant for the duration of the sterilization procedure." Neither Baquey nor Hackett teach or suggest a method for sterilizing a biological material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

D. Field in view of Hackett

The examiner rejected claims 1, 2, 5, 10, 14, 19, 22 and 25-28 under 35 U.S.C. § 102(b) as being anticipated by Field in view of Hackett. The undersigned notes that the examiner erroneously indicated that the present ground of rejection was made pursuant to 35 U.S.C. § 102(b), when it appears that 35 U.S.C. § 103(a) was intended. For instance, the examiner relied upon a combination of references, none of which teach each and every claimed limitation, and the logic of the rejection is predicated on obviousness. Therefore, the undersigned will address this ground of rejection as being made pursuant to 35 U.S.C. § 103(a).

Independent claim 1, from which claims 2, 5, 10, 14, 19, 22 and 25-28 depend, has been amended to recite that the "said effective rate is not constant for the duration of the sterilization procedure." Neither Field nor Hackett teach or suggest a method for sterilizing a biological

material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

E. Sakai or Chanderkar or Field all in view of Hackett and further in view of Horowitz

The examiner rejected claim 3 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sakai or Chanderkar or Field, all in view of Hackett as applied to claim 1, and further in view of Horowitz. Independent claim 1, from which claim 3 depends, has been amended to recite that the "said effective rate is not constant for the duration of the sterilization procedure." None of Sakai, Chandarkar, Field, Hackett or Horowitz teach or suggest a method for sterilizing a biological material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

F. Sakai in view of Horowitz

The examiner rejected claims 30, 34-38, 43-50, 52-54, 57-61, 65-73, 75-77, 80-88, 92-100, 102-104, 107-116, 120-128, 130-132, 135-139, 141-147, 152-159, 161-163, 166-170 and 172 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Sakai in view of Horowitz.

Independent claims 30 and 34, from which claims 35-38, 43-50, 52-54, 57-61, 65-73, 75-77, 80-88, 92-100, 102-104, 107-116, 120-128, 130-132, 135-139, 141-147, 152-159, 161-163, 166-170 and 172 depend, have been amended to recite that "said effective rate is not constant for the duration of the sterilization procedure." Neither Sakai nor Horowitz teach or suggest a method for sterilizing a biological material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

G. Chanderkar in view of Horowitz

The examiner rejected claims 30, 34-40, 46, 48, 49, 51, 53, 54, 57-63, 69, 71, 72, 74, 76, 77, 80-90, 96, 98, 99, 101, 103, 104, 107-118, 124, 126, 127, 129, 131, 132, 135-138, 140, 149, 155, 157, 158, 160, 162, 163, 166-169, 171 and 172 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Chanderkar in view of Horowitz. Independent claims 30 and 34, from which claims 35-40, 46, 48, 49, 51, 53, 54, 57-63, 69, 71, 72, 74, 76, 77, 80-90, 96, 98, 99, 101, 103, 104, 107-118, 124, 126, 127, 129, 131, 132, 135-138, 140, 149, 155, 157, 158, 160, 162, 163, 166-169, 171 and 172 depend, have been amended to recite that the "said effective rate is not constant for the duration of the sterilization procedure." Neither Chanderkar nor Horowitz teach or suggest a method for sterilizing a biological material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of

references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

H. Baquey in view of Horowitz

The examiner rejected claims 30, 34-38, 41, 46, 48-50, 52-56, 58-61, 64, 69, 71-73, 75-88, 91, 96, 98-100, 102-113, 119, 124, 126-128, 130-138, 141-144, 150, 155, 157-159, 161-169 and 172 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Baquey in view of Horowitz. Independent claims 30 and 34, from which claims 35-38, 41, 46, 48-50, 52-56, 58-61, 64, 69, 71-73, 75-88, 91, 96, 98-100, 102-113, 119, 124, 126-128, 130-138, 141-144, 150, 155, 157-159, 161-169 and 172 depend, have been amended to recite that the "said effective rate is not constant for the duration of the sterilization procedure." Neither Baquey nor Horowitz teach or suggest a method for sterilizing a biological material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

I. Field in view of Horowitz

The examiner rejected claims 30, 34, 35, 37, 42, 46, 48, 49, 51, 57, 58, 60, 65, 69, 71, 72, 74, 77, 80-85, 87, 92, 96, 98, 99, 101, 104, 107-113, 120, 124, 126, 127, 129, 132, 135-138, 141-144, 151, 155, 157, 158, 160, 163, 166-169 and 172 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Field in view of Horowitz. Independent claims 30 and 34, from which claims

35, 37, 42, 46, 48, 49, 51, 57, 58, 60, 65, 69, 71, 72, 74, 77, 80-85, 87, 92, 96, 98, 99, 101, 104, 107-113, 120, 124, 126, 127, 129, 132, 135-138, 141-144, 151, 155, 157, 158, 160, 163, 166-169 and 172 depend, have been amended to recite that the "said effective rate is not constant for the duration of the sterilization procedure." Neither Field nor Horowitz teach or suggest a method for sterilizing a biological material wherein the rate of irradiation is not constant for the duration of the sterilization procedure, as presently claimed. Therefore, this combination of references fails to teach or suggest each and every limitation of the present claims. Withdrawal of the outstanding rejection is therefore respectfully requested.

J. New Claims 173-196

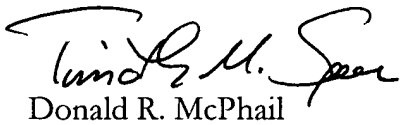
New claims 173-196 each depend from one of independent claims 1, 30 or 34. Therefore, claims 173-196 are allowable over the art relied upon by the examiner in the outstanding office action for at least the same reasons as set forth above regarding independent claims 1, 30 and 34.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that this application is in condition for allowance. Favorable consideration and prompt allowance are earnestly solicited.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this, concurrent and future replies, including extension of time fees, to Deposit Account 16-0607 and please credit any excess fees to such deposit account.

Respectfully submitted,
FLESHNER & KIM, LLP



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